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14. ABSTRACT

To improve care by supporting clinical decision-making by identifying design requirements for computer-based decision support and communication tools, we can describe the Burn ICU (BICU) as a work domain and account for cognitive activities to identify design requirements for a decision support and communication tools using Cognitive Systems Engineering (CSE) methodologies. This project is divided into three phases: foundation research, prototype development, and prototype assessment. In phase I, we conduct one-week data collection visits in a BICU followed by data analysis sessions. Each visit includes: 1) Direct observation of clinical teams providing patient care. Probe questions enable researchers to request background and clarifying information situated in context to better understand motivations, information use, and decision making; 2) Structured interviews elicit knowledge from clinicians about their background, perspectives, work activity, information sources, and challenges they face; 3) Collection of computer-based and hard copy artifacts that clinicians use in their work. These include sign out sheets, personal notes, status boards, and equipment displays, among others. Through data analysis, we develop descriptive models of the BICU work domain and features of clinician decision-making and patient care. These models describe the content and flow of information that the project's prototype decision support and communication system will help to manage.

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Cognitive Engineering, Human Factors

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1. INTRODUCTION AND PROJECT OVERVIEW:

The U.S. Department of Defense maintains one of the largest healthcare networks in the world, supporting in-patient and outpatient care not just for the active military, but their families, reserve forces, veterans, and even civilians local to various military healthcare centers (MHC). As such, each MHC experiences a wide variety of patients and clinical requirements reporting to the many care units in each hospital or clinic. These Care Unit (ICU) patients present healthcare teams with unique challenges and complex combinations of life-threatening injuries and illnesses. Care for these patients is necessarily multidisciplinary. Care providers across professions must collaborate to make effective decisions, develop treatment plans, assess patient progress, and refine management over time. Management decisions, though, are only as good as the information available when they are made. For this reason, the Institute of Medicine recommended improving access to accurate, timely information, and making relevant information available at the point of patient care to improve patient safety. Despite advances in computer systems and knowledge resources, communication failures between resources and healthcare providers continue to cause the majority of misadventures in healthcare delivery: critical information for decision making remains difficult to access and deliver, and is often missing at decisive moments. Healthcare providers in an ICU environment amount to a joint cognitive system that can that can be studied, modeled, and assisted through scientific methods and information technology to improve decision making and thus improve patient care. The daily work of the clinician requires representations as part of this joint cognitive system that serve as a map of the ever-changing environment of work that must be successfully navigated.

The Cooperative Communication System, as we envision it, is part of a joint cognitive system that allows the healthcare team to remain connected to an individual patient and to each other across time and space as the team delivers patient care. As such, it can keep providers informed of a patient's status, of other healthcare providers' activity related to each patient, and of potential discrepancies among healthcare providers' broadly defined, patient driven goals, specifically defined objectives, and individually focused tasks. This type of networked system could also extend beyond the fixed walls of a hospital to incorporate pre-hospital, contingency operations, theater evacuations, etc. For example, when a soldier gets injured, a networked communication system could immediately start relaying information to a Forward Surgical Team or Combat Support Hospital to keep the receiving healthcare team apprised of the patient's status so that they can adequately prepare. Handoff on arrival is then facilitated. The enhanced communication afforded by this system will decrease complications which will directly improve patient outcomes.

In addition to the improved communication between providers, this project explores the potential to provide relevant information to support clinician decision making. The potential exists for the use of artificial intelligence algorithms to display pertinent, prioritized information to a specific healthcare provider to support their current task. As more data becomes available to the AI system during patient care, the CCS will continuously (in real time) improve its availability and priority of the information displayed. This type of decision support should aid care providers from novice medic to experienced physician by expanding support for decision making. Through decision support, patients might receive more accurate and timely diagnoses, more timely and appropriate testing, and best evidence-based care. The time lag from "bench-to-bedside"

treatments can be markedly reduced. We expect the CCS to reduce complications and costs and improve overall patient outcomes via better communication amongst the healthcare team and by dramatically enhancing the availability of optimally prioritized information needed for medical decisions

The Primary Goals of this effort include:

- PHASE 1: Describe patient progress through intensive care to create a shared mental model for clinicians of all specialties;
- PHASE 1: Provide a thorough account of the clinician cognitive work (*i.e.*, work flow and decision requirements) for clinical work in the ICU, including accountability of all pertinent recorded and non-recorded data;
- PHASE 1: Present design requirements for the information, the underlying cognitive networking rules, and the display format of an IT-based cognitive aid for healthcare delivery (the Cooperative Communication System);
- PHASE 1: Derive quantitative evaluation criteria for comparative evaluation of clinical support tools;
- PHASE 2: Present a prototype CCS design for testing and implementation in the USAISR Burn ICU;
- PHASE 3: Develop a test bed based on the clinical environment for Test and Evaluation of the CCS and other clinical support tools.

2. ACCOMPLISHMENTS:

The Phase One/Year One tasks are structured to create a clear understanding of clinician cognition as it applies to the technical work that takes place in the Burn ICU. The major tasks of this phase are:

Task 1.1: Initial Observation of the Burn ICU. Through observation and informal interviews, ARA will identify care activities, workload requirements, decisions in patient care, and the cognitive artifacts clinicians use and create a structured interview guide that will drive the remaining work of this phase.

Task 1.2: CTA Structured Interviews and Observation. ARA will conduct CTA based on the observations from Task 1 and the interview guide. The structured interviews with clinicians will identify the processes, tools and cognitive artifacts, and data they use during their patient care activities.

Task 1.3: Integrated Data Analysis and Model Development. ARA will analyze the data gathered in Tasks 1 and 2 and build valid representations of the cognitive work.

Task 1.4: Decision Model and Design Requirements. ARA will develop specific decision requirements that are necessary for care management in the ICU.

For the past year, primary project effort has been devoted to ARA project staff conducting the week-long data collection site visits to the AISR Burn ICU followed by intensive two-day analysis sessions. These site visit activities are under Task 1.1 and Task 1.2. During the site visit ARA researchers observed Burn ICU personnel and conducted a series of Cognitive Task

Analysis interviews using an interview guide. The interview guide that was initially developed during the second quarter of this research initiative has been revised with each trip allowing researchers to fill in gaps in understanding. Analysis sessions have been dedicated to data review and assessment, and the development of preliminary representations of individual and team cognitive work performed in the AISR Burn ICU, and decision requirements. (Task. 1.3)

The observations and interviews were collected in accordance with the IRB-prescribed procedures to remove all patient personal health information (PHI). The human subjects research protocol is included as Appendix A.

a. Data Collection:

ARA researchers have conducted three week long data collection trips in 2013 during the weeks of March 4-8, May 20-23and July 22-25. The research team on first visit included four members from Cognitive Solutions Division, supported by two members from the ARA San Antonio office. Two CSD members made the trip in May and July.

During each data collection trip the research team conducted Cognitive Task Analysis interviews with members of the AISR Burn ICU clinical and support staff that lasted an average of sixty to ninety minutes.

- March—9 interviews
- May—12 interviews
- July—16 interviews

Team members also circulated through the BICU to observe clinical activities, and occasionally ask informal questions of those who had consented to participate in the study. During the data collection, video records were collected on rounds for two days which resulted in one and a half hours of video. Audio recordings of the interviews were collected if permission was granted for all interviews. Additional data was collected in the form of hand written notes of interviews and observations (which were transcribed), and 19 different types of hard copy and computer-based information artifacts that Burn ICU clinicians and others (including the lab, pharmacy and OR) use.

Each visit provided an opportunity for the team to refine and focus the next collection visit. Seventy products, including interview and observation notes, have resulted from these visits.

A trip report for each of the three data collection visits conducted this year is included as Appendices B, C, and D. Based on the experience of the first data collection visit, the Human Use Protocol was amended to reflect changes and requirements identified during the visit, thus adding ancillary support services to the study.

One more data collection visit is scheduled for November, 2013. This visit will include two to three members of the ARA research team supported by the two staff from the San Antonio office. The purpose of the visit will be to fill gaps in our knowledge about clinical cognitive work using the draft representations and draft design requirements.

b. Data Analysis:

During the reporting period, the ARA team has conducted a series of 2-day data analysis sessions. The first data analysis session was conducted on April 3 and 4. Six team members developed a common understanding of the Burn ICU roles, information sources, and work flow. The session resulted in preliminary representations of the data captured which were subsequently discussed during the second visit with Burn ICU personnel. The research team created a plan for the future data collection visits, including gaps that needed to be addressed during subsequent visits. They also discussed plans for design requirements.

Five team members held a 2-day long data analysis session on June 19-20. The team delved into the collected data to develop cognitive themes and further understanding of the nuances associated with the Burn ICU environment. These findings were used to further refine the interview guide for the third visit with Burn ICU personnel. The session resulted in refinement and development of preliminary representations of the data in the form of diagrams. Preliminary representations included the development of timelines for key personnel of what a typical day's tasks include, a unit map, and interaction with others and when these take place. Other representations include a network diagram of who interacts with a patient on a given day and an aggregated list of who the bedside nurse most frequently communicates. These begin to give us a sense of the key personnel that need to regularly communicate about a given patient and where transfer and flow of patient information from one team member to the next is necessary. Finally, we have begun to construct a representation with all of the information sources available to Burn ICU personnel, who has access to the source, and what type of source it is (e.g. paper, electronic, or other). All of these representations are being iteratively refined and the team will continue to use these in future sites to seek validation and expansion to include missing items from Burn ICU personnel (See Appendix E for first draft representations).

During each data analysis session, the research team created a plan for the future data collection visits to address gaps that needed to be filled during each analysis session. Gaps included the identification key areas of information exchange between Burn ICU personnel (e.g. shift changes, huddles, patient transitions, etc.) where the ARA team would like to do targeted observation. The research team also identified Burn Center personnel with whom they would like to conduct Cognitive Task Analysis interviews beyond those who were interviewed during the first visit. Based on this analysis discussion, the team refined the interview guide to fill knowledge gaps prior to the May and July data collection trips. The team also reviewed alternative approaches to elicit key knowledge from Burn Center personnel. The revised Interview Guide is included as Appendix F.

c. Model Development:

Data analysis meetings have developed both initial descriptions of cognitive work as well as barriers the staff encounter. Both account for themes that appear across the majority of data the team has collected. Appendix G includes themes that have emerged from data analysis that are being used to analyze Year One data.

The onsite research nurse has continued to focus on standard workflow tasks and duties in the Burn ICU while establishing a rapport with staff and key personnel in the ISR, Burn ICU, as well as supporting healthcare providers (e.g., respiratory therapy and rehabilitation staff). The research nurse has also been successful answering numerous questions about the Burn ICU unit as the research team requires. Topics she has assisted include Burn ICU layout, staffing requirements, and standard procedures that are collected and provided to the data collection team. As of August 15, 2013, the research nurse has obtained consent from 137 members of the Burn Center staff.

3. DELIVERABLES STATUS:

Phase One completed and planned deliverables include:

1. Approved Human Subject Protocol: Final approval completed 27 Feb 2013, Amended protocol approved April 30, 2013 (Appendix A)
2. Interview Guide: Developed January 2013, refined May 2013 and re-designed for July 2013 (Appendix F)
3. Visit Reports (x4):
    a. First site visit March 4-8, 2013 (Appendix B)
    b. Second site visit May 20-24, 2013 (Appendix C)
    c. Third site visit July 22-25, 2013 (Appendix D)
4. Burn ICU Cognitive Model: Started, delivery February 2014
5. Burn ICU Metrics: Started, delivery February 2014

The figure below shows the project research schedule in Gantt Chart format. It has been adjusted from the original submission to account for the IRB protocol approval delays.

Task #	Task/Phase Name	Deliverable or Milestone	Year 1				Year2				Year 3			
			1	2	3	4	5	6	7	8	9	10	11	12
Phase 1: Cognitive Systems Engineering														
1	Orientation to ICU Procedures	Structured interview guide												
2	Data Collection	Documented cognitive work in ICU												
3	Data Analysis	Valid descriptive model of the cognitive work												
4	Findings and Design Requirements	Design requirements for the IT-based cognitive aid												
Phase 2: CCS Development														
1	Scoping and Planning	Critical cognitive requirements and detailed softaware requirements documents												
2	Analysis	Preliminary design covering usability indices and approach to software design												
3	Design	User interfaces mockups and detailed software design description												
4	Implementation, Integration and Testing	Initial prototype IT-based cognitive aid												
5	Acceptance and Release	Final prototype CCS												
Phase 3: Laboratory Testing of the CCS														
1	Test Environment Setup	Controlled Test Environment												
2	Evaluation	Interim user evaluation of prototpye against metrics												
3	Validation	Validation study of final prototype system												
4	Assessment	Final usability assessment of prototype												
	Final Deliverable	Tested prototype IT-based cognitive aid for vocational rehabilitation management												

Due to unforeseen challenges in obtaining IRB approval of the Human Use Protocol in the second quarter, the research progress has been delayed by two months. As shown in the Gantt Chart, the first data collection visit, originally scheduled for January 2013, was not possible until March 2013. The research team and AISR agreed to schedule the remaining visits to cover as much as the calendar year as possible. We were able to complete three observation visits within the current POP for Phase One, but for the fourth visit would ideally be scheduled in the first quarter of FY 14. Based on this recommendation and our results from the first two visits, we

have requested an extension to allow for the final data collection visit to occur in November during the first quarter on FY14. The final deliverables for Phase One would also need to be shifted to include the results of this final visit. Phase Two activities started on schedule, as they can start prior to completion of Phase One.

The following activities are planned for September-December 2013:

a. Complete fourth site visit data collection (Task 1.1 &1.2)
b. Conduct data analysis of site visits three and four (Task 1.3)
c. Complete integrated data analysis and model development (Task 1.3)
d. Develop and verify Burn ICU representations (Task 1.3)
e. Create Initial design requirements (Task 1.4)

4. ADMINISTRATIVE

Applied Research Associates, Inc. (ARA) has been under contract W81XWH-12-C-0126 to the U.S. Army Medical Research & Material Command's (USAMRMC) Telemedicine & Advanced Technology Research Center (TATRC) for a year. During the contract period, ARA has worked with the USAISR Quality Review Board and USAMRMC Institution Review Board conducted a routinely scheduled informal review of our research protocol. Prior to the quality review, the research team identified minor protocol deviations and addressed them immediately. The Quality Review Board reviewed and approved the corrections, which were documented in a protocol amendment and submitted to the USAMRMC Institutional Review Board (IRB). The amendment was approved on 30 April 2013 with no deviations or disruptions to the project.

5. EQUIPMENT & SUPPLIES

During the year, the team acquired a video camera, microphone and video editing equipment to document team observations on the BICU.

6. REPORTABLE OUTCOMES

During the reporting period the research team has produced the following professional publications and presentation.

Proceedings

Pamplin J, Anders S, Brown J, Crandall B, Grome A, Chung K, Mann-Salinas E, & Nemeth C. Discovering Complexities in Critical Care and their challenge to Health IT in a Burn ICU. *Proceedings of the Society of Critical Care Medicine 43rd Annual Critical Care Congress*. (*In review*)

Nemeth C, Anders S, Brown J, Crandall B, Grome A, Chung K, Mann-Salinas E, & Pamplin J. Discovery of Burn ICU Critical Care complexities and the Implications for Health IT Design.

Proceedings of the Society of Critical Care Medicine 43rd Annual Critical Care Congress. (*In review*)

Pamplin J, Anders S, Brown J, Crandall B, Grome A, Chung K, Mann-Salinas E, & Nemeth C. Use of Cognitive Systems Engineering to Reveal Burn ICU Decision Making and Information Sources to Aide Health Information Technology Design in the Burn ICU. *Proceedings of the* Submitted to *American Burn Association 45th Annual Meeting*. (*In review*)

Nemeth C, O'Connor M & Pamplin J. Seeking Salience: Improving the Electronic Healthcare Record. *Proceedings of the American Medical Informatics Symposium.* Institute for Healthcare Improvement Symposium 2013. Orlando. (*In review*)

Presentation

Nemeth, C, Foundations of an ICU Decision Support and Collaboration System. Presented at the 2013 Military Health Systems Research Symposium, August 15, 2013. Ft. Lauderdale, FL. (Appendix H)

7. CONCLUSIONS:

CSE study of work and information flow through this DOD critical care facility is producing a descriptive model of patient progress through the ICU, including clinician decision requirements. Phase One activity description of work domain, information source and clinician work practice will serve as the foundation for Phase Two development of a cognitive aid prototype. It has also derived criteria that will be used in Phase Three to evaluate the prototype.

Though the first year of this project was somewhat stalled by the USAMRMC IRB review process the project is now in full swing and after three data collection trips has over 70 transcribed interviews and observations that the ARA research team is currently analyzing and using as the basis for the refinement of the cognitive model of the Burn ICU. The first site visit by ARA to the AISR Burn ICU resulted in a wealth of data. The two subsequent trips have built on that base and further refined our initial understanding and representations of the work that is conducted in the Burn ICU. The third site visit focused on barriers to accomplishing the tasks involved in patient care in the Burn ICU. The analysis of all will continue through December.

The research team has identified themes among the data that account for cognitive work challenges and barriers to patient care. The team is now applying these themes to rigorously analyze collected data. This will allow the team to develop detailed and highly applicable design requirements and cognitive models of the Burn ICU. The final site visit will seek to confirm these results with Burn ICU personnel and adjust them as needed. The remaining data collection and analysis sessions will provide the research team will the opportunity to finalize representations and cognitive models.

Both the ARA and USAISR teams are working well and are highly motivated to accomplish the tasks for Phase One.

Phase Two was started in August in order to keep the project on schedule. The ARA team has also actively engaged with SSCI, our subcontractor for this project, added Josh Blomberg of ARA's Southeast Division to lead interface development, and included Jose Salinas as Phase Two project lead at AISR. The team has begun to identify DoD software development requirements, tasking, and work processes. The slide in Appendix I describes the first draft for a notional software architecture that will encompass SSCI data mining capabilities, the ARA interface, and AISR databases.

As the study continues, the research team will:

- Design and develop a prototype, including ability to mine data for relevant information
- Test and validate the prototype in concert with other IT solutions that are currently in use, Assessment criteria from the first year of research will be used to evaluate prototypes.
- Field in a clinical setting.

The system it produces is expected to improve communication, information flow, and workflow among and across clinical providers and support staff.

U.S. Army Medical Research and Materiel Command
Office of Research Protections
Institutional Review Board Office

HQ, USAMRMC Institutional Review Board

Human Subjects Research Initial Protocol Application – Part C- H-12-042

1. PROTOCOL TITLE: A Cooperative Communication System (CCS) – Version #5 – 05 April 2013

2. ABSTRACT

Intensive Care Unit (ICU) patients present healthcare teams with unique challenges and complex combinations of life-threatening injuries and illnesses. Care for these patients is necessarily multidisciplinary. Care providers across professions must collaborate to make effective decisions, develop treatment plans, assess patient progress, and refine management over time. Management decisions, though, are only as good as the information available when they are made. For this reason, the Institute of Medicine recommended improving access to accurate, timely information, and making relevant information available at the point of patient care to improve patient safety. Despite advances in computer systems and knowledge resources, communication failures between resources and healthcare providers continue to cause the majority of misadventures in healthcare delivery: critical information for decision making remains difficult to access and deliver, and is often missing at decisive moments. Healthcare providers in an ICU environment amount to a joint cognitive system that can that can be studied, modeled, and assisted through scientific methods and information technology to improve decision making and thus improve patient care. The daily work of the clinician requires representations as part of this joint cognitive system that serve as a map of the ever-changing environment of work that must be successfully navigated.

This protocol supports the first phase of a project intended to develop a cooperative communication system (CCS) that is expected to improve patient outcomes by making care more efficient, effective, and less prone to adverse outcomes and misadventures (sometimes referred to as "medical errors"). By describing individual and team care patterns and cognitive work using structured and informal interviews, observation, and artifact analysis, the research team proposes to describe the cognitive work of clinical practice in and around an ICU to guide development of IT systems to help users make better decisions about patient care. During the entire three phase project, the team will describe patient progress through intensive care among clinicians of all specialties; provide a thorough account of the clinician cognitive work (i.e., work flow and decision requirements) for ICU patients; describe the dynamics of how information is captured and shared; account for observed pertinent data that may or may not be entered into formal information systems; develop criteria to evaluate cognitive aid concepts; present design requirements for the content and format of an IT-based cognitive aid for the ICU (the CCS); design and develop a prototype CCS for implementation in the United States Army Institute of Surgical Research Burn Center; Create a laboratory setting to validate the CCS before fielding in an actual clinical setting.

This proposal supports only phase I of the CCS developmental project. In phase I, the research team will describe clinical practice in the Burn Center to identify opportunities for more consistent and efficient patient care. It will reveal important features of the cognitive work that development of an IT-based CCS can support. Findings from data analyses are intended to support development of IT systems that we can evaluate in field and lab settings. This IT-based solution promises to promote established and emerging best practices, real-time monitoring of patient treatment progress, rapid information sharing among clinicians, and efficient training for less experienced care providers. This approach will also enable maximum flexibility for displaying data, relationships, and events that are discovered by the Problem Oriented Information Networking Tool (POINT), a system that actively mines data, identifies relationships, and pushes the right information to the right person at the right time. The CCS will use this to create task oriented, role based gestalt views of the patient that the ICU clinical team can understand and rely on.

Genuine improvements in patient care can be realized through the use of an IT-based cognitive aid such as we propose. Improvements include reductions in treatment/rehabilitation time, reduced burden (both cognitive and workload) on care managers and clinicians, and improved application of best practices. Secondary benefits of these

improvements are also expected to include larger patient throughput for units and reduced cost of care as patients' recovery time is reduced.

3. BACKGROUND AND SIGNIFICANCE

Previous efforts to characterize the cognitive work in the ICU include the work of Marta Render, MD, who has studied related themes in her research at the VA Medical Center in Cincinnati. Recent publications have reported on the work of RNs, communication in acute care, use of bar coding, and clinical reminders. The studies were conducted to identify issues in clinical work settings. Two recent VA ICU studies used retrospective cohort across analyses of variables such as mortality and length of stay. They examined 34 ICUs in 17 VA hospitals in the 2005 study and ICU admissions at 48 VA medical centers in the 2008 study to identify patterns across and among ICUs in the VA system. Our proposed descriptive study will provide a different view of the ICU that can be used along with predictive studies like Render et al, 2005 and Render et al 2008 to calibrate our understanding of how some units achieve better performance than others. The two techniques are entirely complementary, as these studies are broad while our proposed study is deep. One of the likely results of our proposed study will be to provide a better understanding of why the 2005 and 2008 Render studies produced the results they did.

The way a problem is presented can improve or degrade the cognitive work of clinicians because artifacts shape cognition and collaboration. Cognitive artifacts are information displays clinicians develop and use, or are forced to use, and range from checklists to status boards and informal notes. Representations in these artifacts, such as diagrams, organize crucial information to assist cognitive work, from perception to decision making and outcome assessment. Clinicians frequently create, update, and modify their mental models of patients and of unit activity, particularly in complex care settings such as the ICU. Representations can make a task easier by drawing together complex elements of information for clinicians to consider. Representations can also compactly integrate multiple kinds of information. Instead of transferring the decision making to a machine agent (as rule-based programs have tried to do), skillfully crafted representations assist human expert judgment. They do so by portraying, or "re-presenting," the essential elements in a work setting (the "domain semantics") that describe the current state, constraints, goals, and opportunities for action.

Existing representations (especially paper artifacts) combine various important data to allow clinicians to create, update, and evaluate the implications of their mental models. The paper artifacts they create help them to handle the uncertainty and contingencies that are inherent in the acute care setting. More effective representations would spare operators some of the effort of data synthesis by accounting for a wealth of discrete elements through summary, or abstraction. Such representations to aid synthesis would also *enrich operators' ability* to contemplate problems and to envision opportunities. Because of this, effective representations offer substantial potential to benefit clinical care efficiency and improve patient safety.

This program will seek to understand how medical providers across professions interact with each other, their tools, and their environment to provide patient care. As a starter program, it will focus on a patient population of significant military relevance: critically ill surgical, trauma, and burn patients. Each phase will focus on different elements of the healthcare system. The long term goal of this program is to produce a Cooperative Communication System (CCS) that will support clinician cognitive work. In so doing, this CCS will lessen gaps in care continuity. Its use will also promote safe, effective, and efficient patient care without extensive training in new terminology, technology, or practice patterns.

4. MILITARY RELEVANCE

The Cooperative Communication System, as we envision it, is part of a joint cognitive system that allows the healthcare team to remain connected to an individual patient and to each other across time and space as the team delivers patient care. As such, it can keep providers informed of a patient's status, of other healthcare providers' activity related to each patient, and of potential discrepancies among healthcare providers' broadly defined, patient driven goals, specifically defined objectives, and individually focused tasks. This type of networked system could also extend beyond the fixed walls of a hospital to incorporate pre-hospital, contingency operations, theater evacuations, etc. For example, when a soldier gets injured, a networked communication system could immediately start relaying information to a Forward Surgical Team or Combat Support Hospital to keep the receiving healthcare team apprised of the patient's status so that they can adequately prepare. Handoff on arrival is then facilitated. The

enhanced communication afforded by this system will decrease complications which will directly improve patient outcomes.

In addition to the improved communication between providers, this project explores the potential to provide relevant information to support clinician decision making. The potential exists for the use of artificial intelligence algorithms to display pertinent, prioritized information to a specific healthcare provider to support their current task. As more data becomes available to the AI system during patient care, the CCS will continuously (in real time) improve its availability and priority of the information displayed. This type of decision support should aid care providers from novice medic to experienced physician by expanding support for decision making. Through decision support, patients might receive more accurate and timely diagnoses, more timely and appropriate testing, and best evidence-based care. The time lag from "bench-to-bedside" treatments can be markedly reduced. Overall, we expect the CCS to reduce complications and costs and improve overall patient outcomes via better communication amongst the healthcare team and by dramatically enhancing the availability of optimally prioritized information needed for medical decisions.

5. OBJECTIVES/SPECIFIC AIMS/RESEARCH QUESTIONS.

5.1 Describe patient progress through intensive care to create a shared mental model for clinicians of all specialties;

5.2 Provide a thorough account of the clinician cognitive work (*i.e.,* work flow and decision requirements) for clinical work in and around the ICU, including accountability of all pertinent recorded and non-recorded data; Project Objectives not covered by this protocol:

5.3 Derive quantitative evaluation criteria for comparative evaluation of clinical support tools;

5.4 Present design requirements for the information, the underlying cognitive networking rules, and the display format of an IT-based cognitive aid for healthcare delivery (the Cooperative Communication System).

6. RESEARCH DESIGN

The project will schedule regular observations in and around the Burn Intensive Care Unit (BICU) at the primary study location, the United States Army Institute of Surgical Research Burn Center. None of the study activity will interfere with clinical work. In advance of the team's first trip to the site, the study members will informally invite clinical team members to participate and provide a one-page description of the project. No clinician who declines will be asked to participate in an interview or direct observation.

Four team members will travel to the site for the first visit, and two will travel for each subsequent visit. During each trip, the team will confer with the On-site PI, or designee on BICU census and plans for clinical activity. The project will collect data first hand by observing the phenomena that occur while clinicians provide care for ICU patients, studying the ways that practitioners prepare, launch, monitor, adjust, and complete programs of care. The study team will observe and take field notes as clinicians work and interact with one another and occasionally with their patients. Observations may occur in the ICU portion of the burn center or adjacent gym, operating room or hallways. Additionally, two team members will accompany the clinical team on daily rounds, which are typically held outside of each patient room. A video recording will capture for future reference how team members use and share information, including reference to artifacts such as sign-out sheets and task lists. When clinicians interact directly with the patient, audio recordings will be used to capture the methods of communication and information sharing. No video will be taken of patients directly. At the beginning of each trip, the clinical team will take a census of the BICU and ask that each patient or patient representative completes a HIPAA authorization form for use of video and audio recordings. These forms will identify audio and video recording as possible mechanisms for the research study to collect information about how clinicians interact with each other and with patients (Appendix B). A copy of this form will be retained with the study records. Regular Burn Center staff members including nurses, physicians, respiratory therapists, physical and occupational therapists, ward clerks, wound care specialists, and mid-level providers will be asked to complete consent forms before the start of the project (Appendix A). A database for all clinical staff with their consent preferences and unique ID numbers for those who decide to participate will be maintained by the On-site PI or designee. Prior to any observation, transient clinical staff (radiology technicians, consultant physicians, etc.) will be asked to complete a consent form if they are to be observed during their time in the Burn Center. No clinical information or recordings will be taken in the presence of any patient or clinical staff member who declines to participate or complete a HIPAA authorization. Clinical providers and patients may change their preferences about study participation at any time. To identify clinical staff participation preferences, we will

use a color coded card attached to ID badges (green with unique ID number for participants, and absent for undetermined and non-participants). A similar card will be placed on patient identification placards located outside every patient room.

Observation cycles will occur at various times throughout the day and night to sample a range of operational circumstances. These circumstances are expected to range from quiescent routine conditions, to rapid fluctuations such as the admission or discharge of multiple patients, to emergent conditions such as emergencies dealing with cardiac arrest, airway emergencies, hemorrhagic shock, etc.

Observation will also include informal interviews with clinicians that are situated in the context of the work as it occurs in order to obtain information about clinician behavior that cannot be obtained through observation alone. This information includes bases for decisions or apparent indecision, motivations, expectations, and preferences. The field notes that are made during observation will provide data for analysis to derive patterns among and across clinicians. Observations will make it possible to describe the ways that individuals and groups cope with the complexity and uncertainty while they provide clinical care. Potential subjects for attention include an individual's heuristics (rules of thumb), expertise, and knowledge about individual and system performance, human-system interaction, mental simulation, and outcomes assessment. Group activities that the observations can be expected to see include the resolution of discrepancies and conflicts, negotiating trade-offs, evaluation of credibility of data and information from others outside of the unit, and mentoring and coaching activity.

During observations, the team will identify supporting cognitive artifacts that are maintained by and for the group, as well as artifacts that individuals create and use to assist their work. The Over-all PI will describe each artifact in use by individuals and groups in the Burn Center. These will include paper hard copy printouts such as sign out sheets, white marker status boards, and displays on diagnostic and therapeutic equipment. It will also include de-identified personal notes and related items that individuals find helpful that are not part of the formal information ecology. No identifiable personal health information (PHI) will be collected.

The observation period will last one week. The one-week observation periods will be followed by a refractory period of about three weeks during which the investigators will review notes, recordings, and artifacts.

Phase 1, Visit 2, 3, 4, and 5: Two study team members will travel to the site. During the trip, the team will confer with the On-site PI, or designee, on ICU census and plans for clinical activity. At the beginning of the trip, the clinical team will take a census of the ICU and ask that each patient completes the HIPAA authorization. Patients who do not have a HIPAA authorization already on file will be asked to complete one. The two team members will perform observation cycles throughout the 5-day period of the visit as with the initial visit. They will periodically perform informal interviews. During pre-scheduled times, the two team members will also conduct a structured Cognitive Task Analysis (CTA) interview following an interview guide with clinicians who have consented to and scheduled the interview in advance. The structured CTA interviews will be approximately four (4) hours. This interview guide will be developed based on the results of the first observation visit and will be similar to the example interview guide included in Appendix C.

Over the course of a year, this can be expected to result in five weeks of observation in the Burn Center, including periods at night and on weekends. The team will digest notes from field observations and identify patterns that are common to previous cycles. Using cognitive task analysis, the investigator will create models of essential elements (domain semantics) of the ICU work setting. There will also be a dedicated research nurse who will remain on site at the Burn Center for up to 20 hours a week to follow up with clinicians and make interim observations on behalf of the CTA team.

Activities such as observation of individual and group clinical activity and the collection and analysis of cognitive artifacts will provide the basis for analyses that produce accurate descriptions of cognitive work on which representations will be based. Data that are collected during this study (considered Phase 1 of a larger project) will form the basis for hard copy and electronic prototypes that are created in Phase 2 and implemented in Phase 3.

The following table shows the pattern of planning, data collection and analysis.

Time Step	Activity	Details
Initial Visit	**Planning**	**Preparation for in-depth CTA includes:**

		1. Identify and recruit SMEs (clinicians)
		a. Identification of appropriate operational experience, rank, current job function, deployments, education and training
		b. Approximate number of SMEs necessary to provide a representative sampling of relevant task functions, roles, and responsibilities
		c. Scope of data collection: how "big" is the capability gap - how many operational/medical settings, events, and types of clinicians does it involve? How much data will be required to examine the ICU issues?
		2. Data collection requirements, including use of existing data sources and needs for additional data collection
		a. Resource needs for data collection and analysis (funding, availability of SMEs)
		b. The topics and issues data collection must address
		3. Identify appropriate knowledge elicitation and observational methods
		4. Develop data collection protocols (e.g., interview and observation guides)
		a. Resource needs for data collection and analysis (funding, availability of SMEs)
Visit 2-5	**CTA Data Collection**	**Use CTA methods to provide:**
		1. Description of environmental, organizational, and technology challenges the clinician faces
		2. Detailed descriptions of cognitively complex tasks, key decisions, and cognitive processes
		3. Detailed descriptions of the medical environment, event types, roles, and responsibilities
		4. Detailed descriptions of team structure(s), information exchanges, how information flows across organizational components, coordination tasks and communication patterns across individuals and sub-teams
		5. Examples, artifacts, etc.
Between visits	**Analyze CTA Data and Represent Findings**	**Perform in-depth analysis of the CTA data to produce detailed documentation of:**
		1. The set of cognitive work requirements for relevant tasks and operators
		2. Descriptions of team structure(s), coordination tasks and communication patterns across individuals and sub-teams
		3. The technology landscape - the technology context that the materiel solution will operate within, including the tools and technologies currently used in the medical environment, and for what purposes
		4. Medical environment, including key features and constraints
		5. Key design requirements – the critical information elements and operational features that must be present in the technology solution

7. RESEARCH PLAN

7.1 Selection of Subjects

7.1.1 Subject Population. Health care workers and consultants in the United States Army Institute of Surgical Research (USAISR) Burn Center are needed to participate in up to five or more observation periods and cognitive task analysis interviews during year 1 of this study.

Recruitment: Subjects will be recruited from the staff assigned to work in or provide service to patients in the Burn ICU. Local SAMMC/USAISR study staff members will assist with participant recruitment. This process will consist of educational opportunities provided to BICU staff (facilitated through coordination between the clinical and research staff) and individual consent provided after these educational opportunities. One week prior to all study team visits, additional signage will be placed at each entrance to the BICU and Burn Center to remind staff and visitors of the ongoing clinical observation. Study participants will be observed during normal working periods, and will be asked to participate in one to four interviews over the year. Study participants will be identifiable by the presence of green cards on their ID badges. Clinical staff who do not have a card will be cross-referenced to a

master list to confirm his/her participation choice. Individuals who have been approached for consent but who decline participation will be identified on this list maintained by the study team to minimize incidents of re-approaching. When these individuals are present in the clinical observation environment, the study team will not record observations of their activities either by hand or recording device. A HIPAA waiver is submitted with this protocol to allow data collection on patient data that clinicians use to make clinical decisions. This waiver is necessary to allow researchers to capture all relevant information to clinical decision making. Patient data will be collected only for the purpose of understanding why a clinician makes a given decision or to verify that the information the clinician used was indeed the correct information.

Screening: Subjects will be informed about the nature of this project and that their responses to questions may be used during analysis and in presentations or manuscript development. Subjects not wishing to participate are not required to do so.

Patients: Patients (or their surrogate) in the Burn ICU will be asked at the time of admission to sign a HIPAA authorization, and this will be copied and filed with the project records. Patients and/or any family member(s) will be reminded of the study and given the opportunity to decline taping prior to any observation. Patients and their medical information ARE NOT the object of this observational research. Any patient information that needs to be collected will be for example purposes only and used for cognitive task analysis performed for the clinician work in the Burn Center. For patients who are unable to sign the HIPAA authorization, we will ask the surrogate decision maker to complete the form and will follow-up with the patient when/if he/she is able to sign the HIPAA authorization. As de-identified medical information will be collected the On-site PI has completed a Waiver of HIPAA Authorization Request (Appendix D).

Number of Subjects: A minimum of 30 subjects are necessary for the observations and interviews described in Section 6 (above), while 60 unique subjects is ideal. The subjects should include the minimum number of each specialty as identified in Table 2. Since the subjects will be primarily recruited from a fixed working environment, an attrition rate of less than 10% is expected during a single observation period. However, as the five observation periods take place over the course of one year, and the environment includes students and military personnel, an attrition rate between observation periods of over 50% is anticipated. For this purpose, the project will be structured to recruit up to 180 subjects.

Table 2: Breakdown of Subject Specialty.

	Minimum	Target
Burn Surgeon	3	5
Intensivist	2	2
Attending/Staff Physician:	3	10
Physician in Training	0	?
Medical Student:	2	5
Registered Nurse:	3	10
Physician Assistant:	1	2
Medical Technician:	2	4
Respiratory Therapist:	2	4
Occupational Therapist:	2	4
Physical Therapist:	2	4
Wound Care Specialist:	2	2
Radiologist:	2	2
Anesthesiologist:	2	2
Ward Clerk:	1	2
Clinical Nurse Specialist:	1	2
TOTAL:	30	60

7.1.2 Inclusion and Exclusion Criteria.

Inclusion Criteria: Subjects will be all healthcare workers and consultants in the Burn Center (fellows, residents, attending physicians, nurses, respiratory therapist, etc.) being observed in the ordinary course of their work. Subjects

will be recruited by word of mouth by the SAMMC/ USAISR research members.

Exclusion criteria: The exclusion criteria would be a person who chooses not to participate.

Patients: All patients in the Burn ICU, or their legal representative, at the start of an observation period will be asked to complete a HIPAA authorization in the event they are captured by audio or video recording or clinical staff is recorded discussing their medical status if they do not have one on file. If a patient or family member elects not to permit use of their voice or picture, no observation will take place during their treatment. Any medical data necessary for the completion of this observation will be collected without PHI and will only be used as examples of what information clinicians need to do work. All medical data will be de-identified prior to collection, storage, and analysis.

7.1.3 Description of the Recruitment Process.

The On-site PI, or designee, will lead the informed consent process including recruitment, subject screening, and interview. A study team member will conduct an informed consent group brief to the clinical staff during scheduled meetings. Briefings will be scheduled to accommodate shift workers' schedules (day and night shift). Additionally, the study team members will go to work areas and unobtrusively solicit participation of individual clinicians that miss the group brief. They will note that participation is voluntary, and will have no bearing on evaluations. No clinician who declines will be asked to participate in an interview. The ICF is included in Appendix A.

The following script will be posted throughout the Burn Center for one week prior to observation periods and read to subjects solicited for interview (in addition to the formal consent process). The poster is also described in Appendix E.

We are studying individual and team cognitive work in the Burn Center. We would like you to help us by letting us observe you as you perform your work individually and with other staff members. We will not interrupt you as you work. We will not make any record of your name or anything that would identify you in our notes. If you agree to participate, you will be identified by a unique study ID number. We will not record anything that would identify any patient. The notes we take will be used by the research team involved in this project. If you would like at any time to have us stop observing, you may simply tell us and we will leave.

We would like to make audio recordings of these conversations and will ask if appropriate to say aloud what you are thinking. Although your voice would be recorded, we will not identify you in recordings.

A video recording will capture for our future reference how team members use and share information, including reference to artifacts such as sign-out sheets and task lists. When you interact directly with the patient, audio recordings will be used to capture the methods of communication and information sharing. We will be observing what occurs while clinicians provide care for ICU patients, studying the ways that practitioners prepare, launch, monitor, adjust, and complete programs of care.

If you have any future concerns about the observations and recordings made here today, you may contact the Over-all PI, Dr. Nemeth, at 937-825-0707, or the On-site PI, Dr. Kevin Chung, at [210-916-1133].

This study may one day make it possible to better support decision making in the ICU. Your participation in these studies is strictly voluntary and will have no bearing on any evaluation.

Subjects will be observed under normal work conditions (this study is not associated with any specific illness or disease).

Subject will be assigned a unique number to assure protection of their identity and to identify them with any recordings or data collected, but no identifiable information will be collected.

7.1.4 Compensation for participation. None

7.1.5 Consent Process. A study team member will conduct educational events (slide presentation, included in Appendix F, followed-by question and answer period) scheduled through coordination between the clinical staff and on-site study members. Because of the immersive nature of this project – study team members will be present and conducting observations in the work environment during normal work activities – all BICU staff will be in serviced on this project (by roster). Individuals who miss group educational events will be found and educated individually

by the study team. After educational events, staff will be given the opportunity to sign the consent form for participation. The ICF will also include a declination signature line. Staff should sign the ICF indicating either consent to participate or declination from participation. Staff that wish to participate will wear a GREEN card (provided by the study team) on their hospital ID badge. Staff that decline participation will be identified on a list maintained by the study team to minimize incidents of re-approaching. Visual identification devices (badge cards) are necessary for this project so that the study team can quickly identify participating staff and may therefore adjust their observations and recordings accordingly. The green cards will include a unique ID number, which will be the only identification used by the study team to identify participating clinicians. Video recordings that show identifiable features, to include the ID badge, will be obscured with digital blurring. Audio recordings of voices will also be altered to protect the identities of the subjects. Thus once collected, all observational data will not be identifiable to the clinician under observation.

Patients are not the subject of this research project. Therefore, they, or their surrogate decision maker, will be asked to sign a HIPAA authorization in the event that the patient or discussion of the patient's medical status is captured during observational audio or video recordings of study participant(s).

7.1.6 Subject Screening Procedures. See above (section 7.1.1).

7.2 Drugs, Dietary Supplements, Biologics, or Devices. None.

7.3 Study Procedures/Research Interventions. None.

7.3.1 Collection of Human Biological Specimens. None.

7.3.1.1 Laboratory evaluations and special precautions. None.

7.3.1.2 Specimen storage. None.

7.3.2 Data Collection. The project will collect data first hand by observing the phenomena that occur while clinicians provide care for ICU patients, studying the ways that practitioners prepare, launch, monitor, adjust, and complete programs of care. The study team will observe and take field notes as clinicians work and interact with one another and occasionally with their patients. Observations may occur in the ICU portion of the burn center or adjacent gym, operating room or hallways. Additionally, two team members will accompany the clinical team on daily rounds, which are typically held outside of each patient room. A video recording will capture for future reference how team members use and share information, including reference to artifacts such as sign-out sheets and task lists. When clinicians interact directly with the patient, audio recordings will be used to capture the methods of communication and information sharing. No video will be taken of patients directly. When clinicians have time available, two team members will conduct a structured Cognitive Task Analysis (CTA) interview following an interview guide. The Interview Guide will be developed based on the initial observations conducted during the first visit, and example from a previous CTA interview is included in Appendix C.

7.3.2.1 Video and Audio Recording. All video and audio recordings will be taken with a standard compact HD video camera and recorded on an SD memory card. The recordings will be taken by the five members of the study team. Within 7 days following recording, the video and audio records will be edited by ARA and USAISR staff members to remove Personally Identifiable Information (PII) via selective deleting or obscuration using video editing software while on site. All de-identified recordings will be stored on an encrypted password-protected file and/or locked in a file cabinet located at the USAISR or ARA Cognitive Systems Division Headquarters. Audio recordings will be secured in the same manner until completion of transcription. Transcription of recordings will take place within 60 days of collection and then destroyed following the completion of analysis. Recordings will be used as described in Section 6 to build the cognitive model of the Burn ICU.

7.3.3 Human Biological Specimens/Tissue/Data Banking. HIPAA authorization documents & consent forms will be stored in a locked file cabinet for six years after which the information will be shredded.

No electronic files will contain personal information. Electronic files will only include a subject identification number. Subjects will not be identified by name, only by role (i.e. surgeon, intensivist, nurse, etc.).

7.4 Statistical Consideration

7.4.1 Sample Size Estimation. As a qualitative, observational study, and statistical power analysis does not apply.

7.4.2 Primary (i.e., primary outcome variables) and secondary endpoints. Not applicable to a qualitative study.

7.4.3 Data analysis. The objective of the data analysis is to identify patterns that are common to clinical work in the Burn Center. Using cognitive task analysis, the investigator will create models of essential elements (domain semantics) of the ICU work setting. An example of such a model, although very simple and not the target of this work, is a staffing schedule. The study is descriptive and as a result analysis procedures are not statistical in nature. The models developed during the analysis will clarify where there are gaps in knowledge, problem areas for clinicians in their decision making processes, opportunities to improve decision making processes, and cognitive work that is particularly amenable to improvement through computer-based representations. This is a discovery project in which team members learn while performing the research and build the analysis organically. That is, the analysis methods used are appropriate to the data collected.

7.7 Confidentiality. Audio and video records will be recorded so as not to identify the practitioners when possible. Should identifying data be inadvertently recorded, it will be edited within 7 working days. The data will be stored in a locked storage area accessible only to the study team members and labeled as quality assurance material. A master list of the unique ID numbers assigned to study participants will be created and maintained in a password protected electronic file, only accessible to study team members. The electronic file will be maintained on a dedicated laptop hard drive used for project files. When not in use, this hard drive will be stored in a locked file cabinet with hard copy documents in the USAISR.

Accurate and complete study records will be maintained and made available to representatives of the U.S. Army Medical Research and Materiel Command. These representatives are authorized to review project records as part of their responsibility to protect human volunteers. Records will be stored in a confidential manner so as to protect the confidentiality of subject information.

7.7.1 Certificate of Confidentiality. Not Applicable.

8. RISKS/BENEFITS ASSESSMENT

8.1 Risks. There are no direct health risks associated with participation in this study. There is a slight risk of discomfort or anxiety that one's care patterns or style will be judged or that errors will be captured during the observation and recording that can result in adverse professional or administrative action. The clinicians that participate will be assured that his/her observed behavior will be de-identified and there will be no personally identifying characteristics collected with the data. De-identified video/audio may be discoverable evidence for legal or administrative purposes, however through the de-identification process (blurring of faces, badges, name tags, etc. and tonal shifting of voice), discoverable recordings should not be personally interpretable. There may be a slight risk of loss of confidentiality or interruption of work during the observation periods.

8.2 Potential Benefits. This study is not being done to improve the immediate condition or health of the subjects. Subjects will benefit only through the possible improvement of work done in the Burn Center as a result of these observations.

9. ADVERSE EVENTS, UNANTICIPATED PROBLEMS, AND DEVIATIONS

9.1 As this study at present involves only observational data collection and interviews with the health care providers, we do not anticipate adverse events associated specifically with this protocol.

Suspensions, clinical holds (voluntary or involuntary), or terminations of this project by the IRB, the institution, the Sponsor, or regulatory agencies will be promptly reported to the USAMRMC ORP IRBO and HRPO.

Any deviation to the protocol that may have an adverse effect on the safety or rights of the subject or the integrity of the study must be reported to the IRBO and HRPO as soon as the deviation is identified. The adverse event reporting form is included in Appendix G.

9.2 Reporting Unanticipated Problems Involving Risks to Subjects or Others, Serious Adverse Events and Deaths to the HQ, USAMRMC IRB.

All unanticipated problems involving risk to subjects or others, serious adverse events, and all subject deaths will be promptly reported by phone (301-619-6240), by e-mail (IRBOFFICE@amedd.army.mil), by facsimile (301-619-4165) to the HQ, USAMRMC IRB,

or sent to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RP, 504 Scott Street, Fort Detrick, Maryland 21702-5012. A complete written report will follow the initial notification.

9.3 Research Monitor. No research monitor is required for minimal risk studies.

10. WITHDRAWAL FROM STUDY PARTICIPATION. Subjects are permitted to withdraw from the study at any time. They merely have to express their verbal desire to withdraw and observations and recordings of their activities will cease immediately. All efforts are made to collect data in a de-identified manner such that data associated with any participant should not be identifiable.

11. USAMRMC Volunteer Registry Database. NA

12. REFERENCES

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13. TIME REQUIRED TO COMPLETE THE RESEARCH (including data analysis). 12 months

APPENDIX A: INFORMED CONSENT FORM (ICF)

APPENDIX B: HIPAA AUTHORIZATION

APPENDIX C: SAMPLE INTERVIEW GUIDE

APPENDIX D: HIPAA WAIVER REQUEST

APPENDIX E: RECRUITMENT ADVERTISEMENTS

APPENDIX F: PARTICIPANT EDUCATION MATERIALS

APPENDIX G: SERIOUS ADVERSE EVENT REPORT FORM

For the purposes of this form, a serious adverse event is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, causes persistent or significant disability/incapacity, results in congenital anomalies/birth defects, or in the opinion of the investigators represents other significant hazards or potentially serious harm to research subjects or others. A serious adverse event is considered unexpected if it is not described in the protocol, or in the informed consent document.

<table>
<tr><td>PROTOCOL #:____ - ____- _____</td><td colspan="2">PROTOCOL TITLE:</td></tr>
<tr><td>PRINCIPAL INVESTIGATOR:</td><td colspan="2">Institute: Office Phone:
Fax: E-mail:</td></tr>
<tr><td>DATE OF SERIOUS ADVERSE EVENT:</td><td colspan="2">____/____/_____</td></tr>
<tr><td>LOCATION OF SAE (e.g., at NIH or elsewhere):</td><td colspan="2"></td></tr>
<tr><td>WAS THIS AN UNEXPECTED ADVERSE EVENT?</td><td colspan="2">Yes [ ] No [ ]</td></tr>
<tr><td>BRIEF DESCRIPTION OF SUBJECT(S) (Do NOT include identifiers.)</td><td colspan="2">SEX: M/F AGE: _____
Diagnosis:</td></tr>
<tr><td colspan="3">BRIEF DESCRIPTION OF THE NATURE OF THE SERIOUS ADVERSE EVENT:</td></tr>
<tr><td>CATEGORY (outcome) OF THE SERIOUS ADVERSE EVENT:
[ ] death
[ ] disability/incapacity
[ ] life-threatening
[ ] congenital anomaly/birth defect
[ ] hospitalization-initial or prolonged
[ ] required intervention to prevent permanent impairment
[ ] other</td><td colspan="2">RELATIONSHIP OF SERIOUS ADVERSE EVENT TO RESEARCH:

[ ] 1 = unrelated (clearly not related to the research)
[ ] 2 = unlikely (doubtfully related to the research)
[ ] 3 = possible (may be related to the research)
[ ] 4 = probable (likely related to the research)
[ ] 5 = definite (clearly related to the research)</td></tr>
<tr><td>HAVE SIMILAR ADVERSE EVENTS OCCURRED ON THIS PROTOCOL?</td><td colspan="2">Yes [ ] No [ ]
If “Yes”, how many? _____
Please Describe:</td></tr>
<tr><td>What steps do you plan to take as a result of the adverse event reported above? Provide documentation to the IRB for review and approval of any of the steps checked below.</td><td colspan="2">[ ] no action required
[ ] amend consent document
[ ] amend protocol
[ ] inform current subjects
[ ] terminate or suspend protocol
[ ] other, describe:</td></tr>
<tr><td colspan="2">INVESTIGATOR’S SIGNATURE:</td><td>DATE:</td></tr>
</table>

APPENDIX H: REQUEST FOR EXPEDITED REVIEW

Expedited review is requested because the following conditions are met:

1. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: Physical sensors applied to the surface of the body not involving input of significant amounts of energy or an invasion of privacy.

2. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior),

Appendix B-AISR Trip Report 4-8 Mar 2013

8 March 2013

From: Christopher Nemeth, PhD
To : Betty Levine, TATRC
Cc : LTC Elizabeth Mann-Salinas, US Army Burn Center

Subj : Trip report : AISR Data Collection 4-8 March 2013

Encl : (1) Research Team Schedule

1. Executive Summary. Applied Research Associates, Inc. (ARA) is under contract W81XWH-12-C-0126 to the U.S. Army Medical Research & Material Command's (USAMRMC) Telemedicine & Advanced Technology Research Center (TATRC). The Cooperative Communication System is intended to be part of a joint cognitive system that allows the healthcare team to remain connected to an individual patient and to each other across time and space as the team delivers patient care. In addition to the improved communication between providers, this project explores the potential to provide relevant information to support clinician decision making. Data collection visits during Year One will provide the descriptive model and decision requirements for Year Two prototype development.

2. Staff. Four members of the Applied Research Associates research team made this trip to San Antonio : Shilo Anders, PhD, Jeffrey Brown, Christopher Nemeth, PhD and Sandra Stankovic.
Two team members from the ARA San Antonio office also supported the visit: Greg Rule and Dianne Hancock.

3. Activities. All information was collected in accordance with IRB-prescribed procedures to remove patient personal health information.

a. Orientation. Received an orientation on Monday morning from MAJ Pamplin to the AISR Burn ICU physical facility and staff members.

b. Interview. Conducted nine structured cognitive task analysis interviews lasting an average of sixty to ninety minutes each with members of the AISR Burn ICU clinical staff in the following roles:

4 March	Assistant Head Nurse
	Bedside Nurse/Charge Nurse
5 March	Wound Care Clinical Specialist
	Dietician
6 March	Staff Support Psychiatric Nurse
	Surgical Resident
7 March	Chief, Occupational Therapy
	Chief Nursing Officer 4T
8 March	Chief Nursing Officer 4E

c. Observation. Team members circulated through the BICU to observe clinical activities, and ask occasional informal questions of those who had consented to participate in the study.

d. Task Area Manager Meetings. Dr. Nemeth met with Task Area Manager Dr. Mann-Salinas to discuss Phase One, and Task Area Manager Dr. Salinas to discuss planning for Phase Two.

4. Results. The research team developed a number of work–in-progress items to begin concept development, support data analysis, and prepare for the next data collection visit.

a. Interview notes. In-depth notes accounting for data that were collected according to the Interview Guide, for each of the Cognitive Task Analysis interviews.

b. Observation notes. Notes team members made during observations and brief discussions with members of the BICU clinical staff.

c. Rough diagrams. Initial representations of the timeline, network, and information sources derived from interviews and observations.

5. Further work. Next steps for the project will be to :

a. Review results from this data collection visit, including any needed transcriptions

b. Analyze data using in-progress diagrams

c. Plan next data collection visit for May 2013

6. For further information, contact Dr. Nemeth at 937-825-0707, or cnemeth@ara.com.

Appendix C-AISR Trip Report 20-24 May 2013

30 May 2013

From: Chris Nemeth, PhD
To : Betty Levine, TATRC
Cc : LTC Elizabeth Mann-Salinas, US Army Burn Center

Subj : Trip report : AISR Data Collection 20-23 May 2013

Encl : (1) Research Team Schedule

1. Executive Summary. Applied Research Associates, Inc. (ARA) is under contract W81XWH-12-C-0126 to the U.S. Army Medical Research & Material Command's (USAMRMC) Telemedicine & Advanced Technology Research Center (TATRC). The Cooperative Communication System is intended to be part of a joint cognitive system that allows the healthcare team to remain connected to an individual patient and to each other across time and space as the team delivers patient care. In addition to the improved communication between providers, this project explores the potential to provide relevant information to support clinician decision making. Data collection visits during Year One will provide the descriptive model and decision requirements for Year Two prototype development.

2. Staff. Two members of the Applied Research Associates research team made this trip to San Antonio: Shilo Anders, PhD and Jeffrey Brown. Two team members from the ARA San Antonio office also supported the visit: Greg Rule and Dianne Hancock.

3. Activities. All information was collected in accordance with IRB-prescribed procedures to remove patient personal health information.

a. Re-Orientation. The ARA team was re-introduced to the AISR Burn ICU staff members and research staff assisting with the project.

b. Interviews (Task 1.2). The ARA team conducted twelve structured cognitive task analysis interviews lasting an average of sixty to ninety minutes each with members of the AISR Burn ICU clinical staff in the following roles:

20 May	Pharmacy Supervisor
	Senior Burn ICU Volunteer
	Lead Lab Technician
21 May	Infection Prevention Nurse
	Charge Nurse (stepdown & ambulatory)
	Chief Nurse
	Senior Burn ICU Volunteer
22 May	NCO Wardmaster
	Charge Nurse 4T
23 May	Volunteer Coordinator
	Wound Care Specialist
	Bedside Nurse & CRRT Trainer

c. Observations (Task 1.2). During this visit, team members circulated through the BICU to observe clinical activities, and ask occasional informal questions of those who had consented to participate in the study. Additionally, team members conducted targeted shadowing with bedside, charge and wound care nurses, physical and respiratory therapists, and ancillary personnel (e.g. lab and pharmacy). These sessions involved shadowing a single person for 1.5 hours to 3 hours and asking them to think aloud as they completed their work. Additionally, the researcher would ask questions about what they were doing as well as occasional questions from the semi-structured interview guide.

d. USAISR Update Meeting. While on site, a teleconference was held with LTC Pamplin, Dr. Mann-Salinas (Task Area Manager, Phase One), Nicole Caldwell, the ARA team including Project PI, Dr. Nemeth to discuss the visit status and next steps of the study.

4. Results. The research team developed a number of work-in-progress items to continue concept development, support data analysis and integration with prior visit material. The data will inform the next data analysis session, which is scheduled for June. Additionally, the presence and rapport building with AISR Burn ICU staff continued and will assist in preparing for the next data collection visit.

a. Interview notes. In-depth notes accounting for data that were collected according to the Interview Guide, for each of the Cognitive Task Analysis interviews at in the process of being transcribed.

b. Observation notes. Notes team members made during observations and brief discussions with members of the BICU clinical staff are being transcribed for further analysis.

c. Rough diagrams. The research team is refining initial representations of the timeline, network, and information sources derived from interviews and observations based on the new information collected during this visit.

5. Further work. Next steps for the project are:

a. Review results from this data collection visit, including any needed transcriptions

b. Analyze data using in-progress diagrams and for emergent themes

c. Plan next data collection visit for July 2013

6. For further information, contact Dr. Nemeth at 937-825-0707, or cnemeth@ara.com.

Appendix D-AISR Trip Report 22-25 July 2013

30 May 2013

From: Chris Nemeth, PhD
To : Betty Levine, TATRC
Cc : LTC Elizabeth Mann-Salinas, US Army Burn Center

Subj : Trip report : AISR Data Collection 22-25 July 2013

Encl : (1) Research Team Schedule

1. Executive Summary. Applied Research Associates, Inc. (ARA) is under contract W81XWH-12-C-0126 to the U.S. Army Medical Research & Material Command's (USAMRMC) Telemedicine & Advanced Technology Research Center (TATRC). The Cooperative Communication System is intended to be part of a joint cognitive system that allows the healthcare team to remain connected to an individual patient and to each other across time and space as the team delivers patient care. In addition to the improved communication between providers, this project explores the potential to provide relevant information to support clinician decision making. Data collection visits during Year One will provide the descriptive model and decision requirements for Year Two prototype development.

2. Staff. Two members of the Applied Research Associates research team made this trip to San Antonio: Shilo Anders, PhD and Jeffrey Brown. Two team members from the ARA San Antonio office also supported the visit: Greg Rule and Dianne Hancock.

3. Activities. All information was collected in accordance with IRB-prescribed procedures to remove patient personal health information.

a. Re-Orientation. The ARA team was re-introduced to the AISR Burn ICU staff members and research staff assisting with the project.

b. Interviews (Task 1.2). The ARA team conducted sixteen semi-structured cognitive task analysis interviews lasting an average of thirty to forty-five minutes each with members of the AISR Burn ICU clinical staff in the following roles:

22 July	Licensed Social Worker
	License Vocational Nurse
	Registered Nurse
	Registered Nurse
23 July	Registered Nurse
	Clinical Nurse Specialist
	Resident
24 July	Resident
	Respiratory therapist
	Registered Nurse
25 May	Chaplain
	Clinical Nurse Specialist

Licensed Vocational Nurse
Rehab. Provider
Respiratory Therapist
Registered Nurse

c. Observations (Task 1.2). During this visit, team members circulated through the BICU to observe clinical activities, and ask occasional informal questions of those who had consented to participate in the study. Additionally, team members conducted targeted shadowing with bedside, charge and wound care nurses, and physical and respiratory therapists. These sessions involved shadowing a single person for 15 minutes to 60 minutes and asking them to talk aloud as they completed their work. Additionally, the researcher would ask questions about what they were doing as well as occasional questions from the semi-structured interview guide.

4. Results. The research team developed a number of work-in-progress items and initial emergent themes drawn from the interviews to further concept development, support data analysis and integration with prior visit material. The data will inform the next data analysis session, which is scheduled for August. Additionally, the presence and rapport building with AISR Burn ICU staff continued and will assist in preparing for the next data collection visit, which is scheduled for early November.

a. Interview notes. In-depth notes accounting for data that were collected according to the Interview Guide, for each of the Cognitive Task Analysis interviews have been transcribed.

b. Observation notes. Notes team members made during observations and brief discussions with members of the BICU clinical staff have been transcribed for further analysis.

c. Rough diagrams. The research team is refining initial representations of the timeline, network, and information sources derived from interviews and observations based on the new information collected during this visit. The team is also developing other representations based on the information collected, such as the development of a wheel showing who the nurse talks with during the course of their day and challenges for sensemaking and memory.

5. Further work. Next steps for the project are:

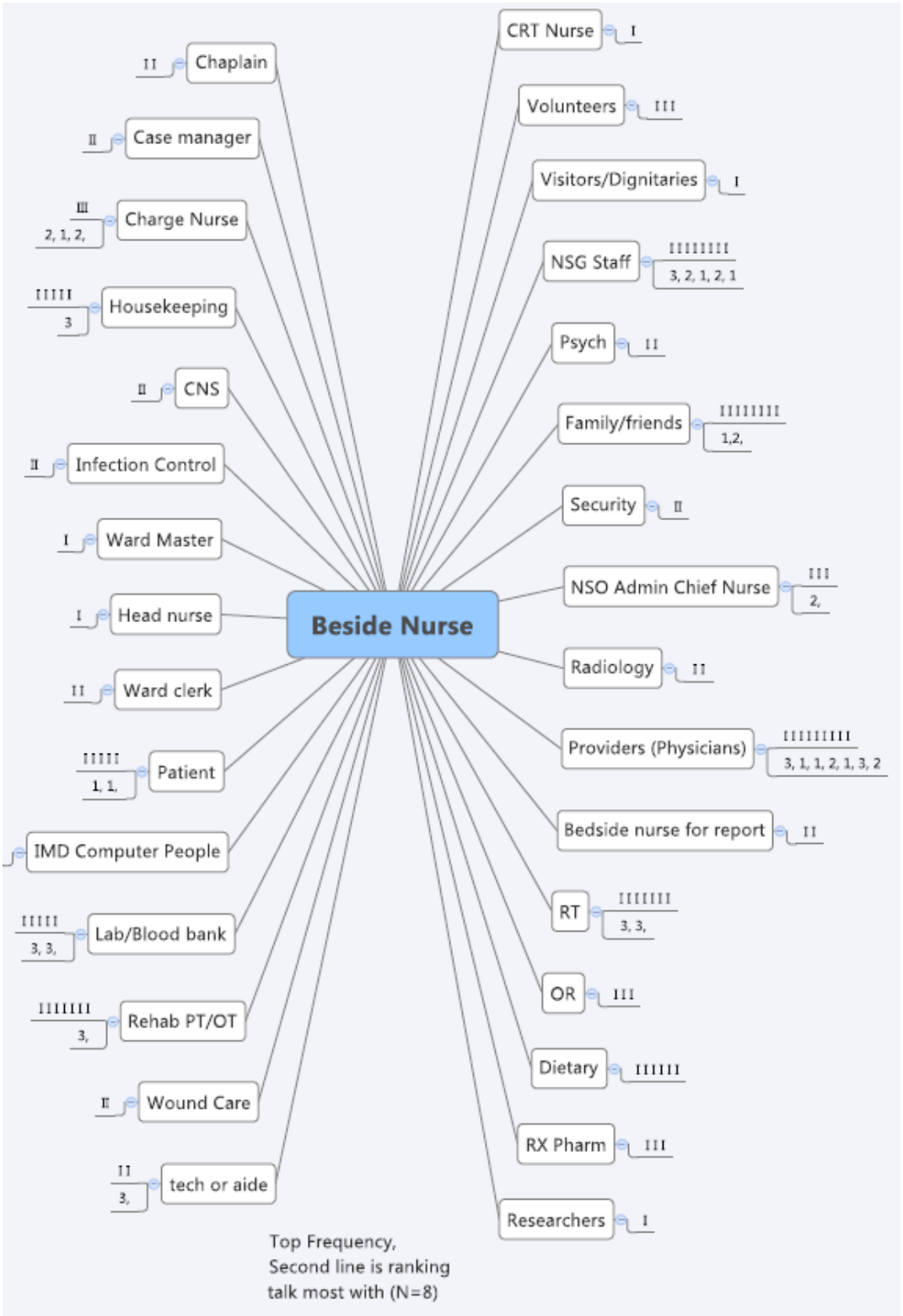
a. Review results from this data collection visit, including any needed transcriptions

b. Analyze data using in-progress diagrams and further define emergent themes

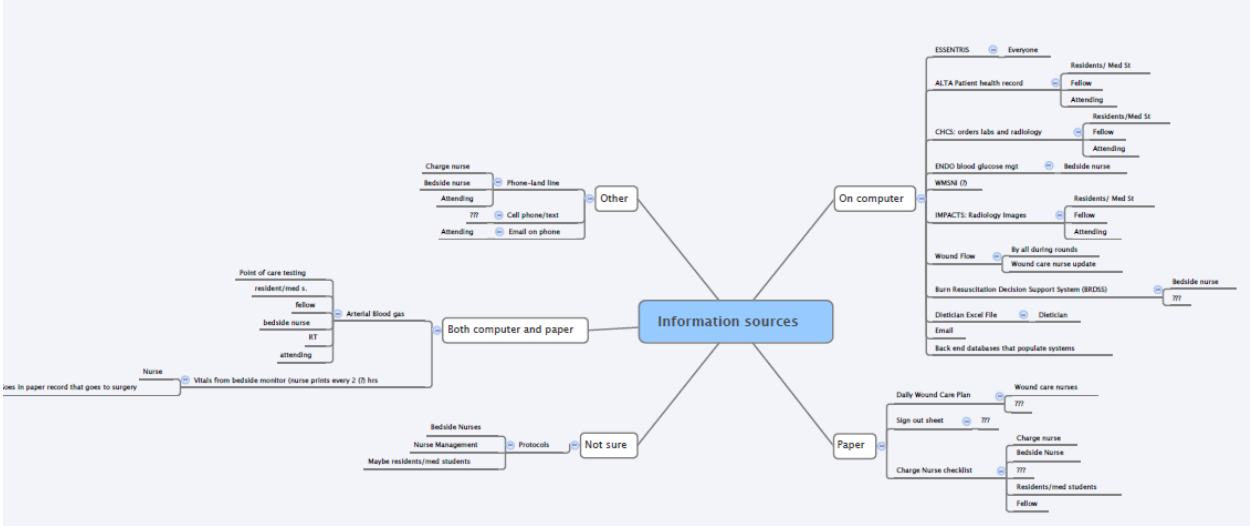
c. Plan next data collection visit for November 2013

6. For further information, contact Dr. Nemeth at 937-825-0707, or cnemeth@ara.com.

Appendix E – First Draft of Representations



Communication and coordination around the bedside nurse.



ICU Information Sources.

BICU Timeline Weekdays

Time	Activity	Participants	Information Resource
0000-0645	Patient monitoring, occasional medication	Bedside nurse; resident	Patient monitors
0630-0800	Patient Exam, Rounds preparation	Resident, medical student	Signout sheet; Essentris, IMPACT, Wound Flow, Patient monitors; Bedside nurse, offgoing resident
0645-0700	Safety huddle	Asst Head Nurse, oncoming bedside nurses	Personal notes
0700-0800	Bedside report and physical assessment	Offgoing bedside nurse, oncoming bedside nurse	Patient monitors
0700	ICU audit	Asst Head Nurse	Personal Notes
0700-0730	Metabolic assessment	Dietician	Excel file; eCentris EHR
0800	Patient Rounds	Intensivist, burn surgeon, fellow, resident, bedside nurse, charge nurse, medical student, respiratory therapist, occupational therapist, social worker, dietician,	Electronic health record,
0800-1400	Shower, Wound care	Bedside nurse, Wound care team: RN and LVN	Wound Flow
0800-1400	Medications	Bedside nurse	
0800-1400	Surgeries	Burn surgeon, OR team	Shadow chart(?)
~1400	Patient exam (?)	Resident (?)	
1200-1300	Lecture	Staff physician, surgical and medical residents, medical students	
~1500	Afternoon Rounds		
1530	Plan for wound care next day	Charge Nurse, wound care coordinator	4T Assignments sheet

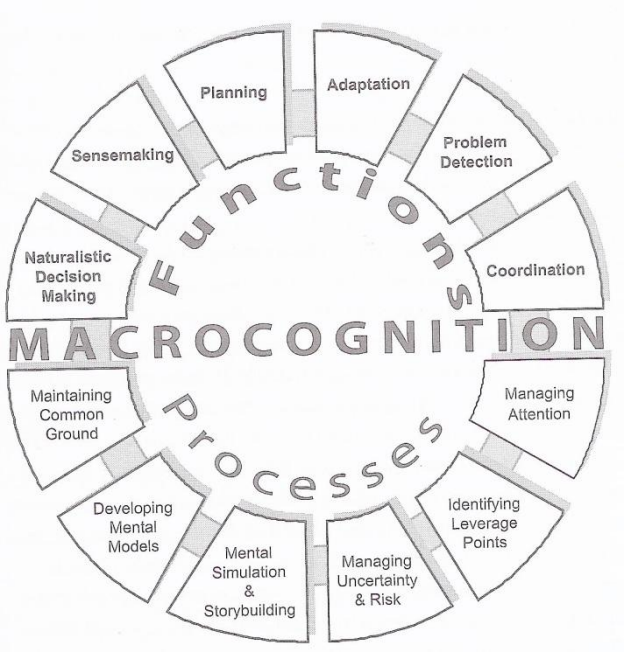
Timeline.

Appendix F--CCS Initial Model Development

CCS Model Development

Development of a model to represent cognitive challenges and barriers in the Burn ICU is to identify cognitive work that clinicians perform.

Cognitive work can include the range of macrocognitive activities that Crandall et al (2006) described, as the following diagram describes.



Cognitive systems engineering also reveals barriers to clinical work that might be aided or mitigated by use of the CCS cognitive aid.

These initial themes and barriers have evolved from data analyses and are being used to rigorously analyze data collected since March.

Cognitive work

Initial review of the data suggest a number of macrocognitive activities by individuals and groups.

Table 1: Emergent themes for Cognitive work of Burn ICU

Theme	*Definition*
Rework	Bridging and workaround strategies to link systems that don't talk to each other.
Information continuity	ABG does/doesn't connect to electronic Patient Health Record. Additional volume needs to be created for long-term patient.
Negotiation	Among individuals, specialties, levels of expertise dynamic requiring negotiation hourly/by shift/daily.
Scheduling	Planning, re-planning among, across patients and specialties.
Anticipation	Patient status, needs and how to meet them. Preparation and participation in events.
Coordination	Collaboration requires expression of expectations, prioritization, agreement, recruitment/transfers.
Clarification	Inquiry, sense making, common grounding to reach threshold of confidence to accept responsibility drives down level of uncertainty.
Resources	Access. Availability. Permission. Provision. Preparation. Authority. Certification. Use ["Technical Work"]
Tasking	Assignment of ICU staff to best match patient needs. Individual abilities/experience. Team needs.
Cross Check	Identify/confirm/correct information problem detection. Does it create drag?
Tracking	Account for what needs to be done, whether it has been completed, what remains to be done.
Gaps	Ability to see "what isn't there"

Challenges

A number of work domain issues detract from the time and effort that could be devoted to patient care. The research effort considers each from the viewpoint of whether the cognitive aid could play a role to either mitigate or eliminate them.

Table 2: Emergent themes of Barriers and Challenges to effective care

Theme	Definition
Limited orientation	Of residents and float RNs. RN's fill gap-takes time from patient care
Lags in info: meds, labs, & blood	Rely on verbal orders: "on sly" not fully socialized/shared; consistent care delays
Bedside nurse reconciles conflicts	Technology protocol, guidelines, policy, rebs vs patient care needs (e.g. Mixing ketamine, consult note conflicts)
Procedural Drag	Transcription. Work-arounds due to system organizational gaps
Reliance on memory as failure marker	Technology fails to support needed work. E.g. afternoon rounds not fed forward to next day
Story of the patient/big picture lost	Trend info, understanding lost/degraded over long term of care, no synthesis
Reliance on verbal exchanges	Info flow porous, brittle, not shared, not reliable (e.g. Acinetobacter treatment event); patient admission
Authority gradient	Encourages passivity WRT concerns; impediment to sharing
Common grounding accuracy	Under specification, confirmation, verification, clarification; decay in treatment, charge nurse may/may not address at team level
Action/Who has the CON?	Specialties, but no accountability on team to assure results
Timing	Lack of synchrony, stale info; e.g. when procedure was performed.
Salience	Homogenous info. Most relevant info is hard to find; stat orders not evident
Usability/access/usefulness	Software access, requisite operator knowledge, incorrect entry (e.g. wound flow)
Organizational issues=drag	Compliance with admin reminders

Appendix G-CCS Interview Guide July 2013

Interview Guide : July 2013 Data Collection Trip

Goals: Identify and obtain a detailed account of an event/incident that conforms to the following criteria:

- A challenging incident in which
  - Team members had to struggle to figure out what was happening over a period of time (team sensemaking challenges).
  - Team members were surprised by how events unfolded
  - A team member(s) had significantly different understanding of the patient's status than other team members.
  - The team's collective understanding of the situation changed significantly during the incident
  - The team aspect was important in eventually understanding the situation
    - Even if the team didn't work well together- if these incidents will highlight issues the clinical unit is facing.
- An incident that reflects breakdowns in common ground (interpredictability, shared understanding/assumptions regarding situation...).

Introductions*: (reiterate for those interviewed on prior trip)*

We're from Applied Research Associates. Our project team is developing an information display to support clinician decision making, communication, and coordination. We are interviewing experienced clinicians to gain an understanding of how work is currently performed and how information is exchanged across the clinical team in the BICU. We will apply what we learn from you to the development of design requirements for a clinical decision aid. We hope to have ____ of your time… is that going to work for you?

- ***State***
  - *We will not use any specific names in reporting the data, or identify you in any way*
  - *We would like to audiotape the interview; use it as a backup to our notes, will not share the audiotape beyond the research team.*

Questions? (give them a business card)

Section I:	**SME Background and Tasks (If not acquired on first data collection Trip, or if deepening is warranted)**
Overview	**SME Background** • Role/position (attending, fellow, resident, intern, nurse, respiratory therapist, etc.) • Experience prior to current role? • Length of experience in current position? • Length of experience in the BICU? • Length of time at BAMC?
Section II:	***Incident Identification***
Incident	**Possible queries** • Can you think of a recent time when you and other care providers were really challenged in caring for a patient—in making sense of one of your patient's situation/condition and how to address it? • Can you think of a time you (or the entire team) were surprised by how events unfolded in the care of a patient? • Can you think of a time when your understanding the patient's status was significantly different than others on your team? • Can you think of a time when your team had a big disconnect (coordination, understanding the patient's situation and care requirements…)?

	• **Listen for:** ○ Challenges in understanding the situation ○ Incidents in which understanding of the situation changed ○ Information gaps/lags; problems with information timeliness or integrity. ○ Team coordination challenges. ○ Different interpretations/understanding across team members • **Ask** ○ Ask the interviewee to describe her understanding of the situation before the incident/event began to unfold. For example, the care plan that was in place for this particular shift, before this situation began.
Section III:	***Timeline***
	Timeline ○ **Ask the interviewee to go back over the incident—** ▪ initial understanding of situation (status quo) ▪ event and the understanding of the unfolding situation ▪ changes in situation assessment ▪ resolution / return to status quo. ▪ Who involved in incident? (key players) ▪ **Repeat back the incident** ❖ Articulate key changes in assessments, the interviewee's suspicions of what was happening and why; surprises, and major events. . • **Ask clarifying questions to elicit such things as** ❖ What info needed and why? ❖ Where (or from whom) (and when) was information accessed/sought? ❖ How they modified/added to the info (if at all) before using it or sharing it w/others ❖ Barriers to info access or info interpretation ❖ How might physical location (on/off unit) have helped or hindered? ❖ Cues and Clues to change in situation…
Section IV:	***DEEPENING***

The Story behind the story.	**Goal:** • **Ask questions until you understand the incident and 'information space', i.e., data available, means of obtaining data, challenges making sense of the data.** o Listen for missing data, ambiguous cues, violated expectancies, surprises. o Listen for strategies for information gathering and interpretation. o Listen for novice-expert differences; potential errors, alternative decisions o Work backwards from the surprise or shift in understanding. o Use the timeline for organizing the incident and your lines of questioning. o Repeat back confusing/ambiguous statements • **Anchor question to points in the timeline:** o **<u>Goal</u>** o What were you trying to accomplish at this point? o **<u>Understanding of the situation</u>** ▪ What was your understanding at this point in time? ▪ What about the situation let you know what was going to happen? ▪ What were you noticing at this point? ▪ What were your concerns at this point? ▪ How did you think things would play out at this point?

The Story behind the story.	○ **<u>Cues and knowledge—per points on the timeline</u>** ○ What were you noticing at this point (senses—seeing, hearing,…)? ○ What information did you use in making decisions—where did you get this information? How did you use that information? ○ Was there information you needed, but could not obtain, or that was too ambiguous? ○ **<u>Coordination and information sharing</u>** ▪ Who did you share the info with? How? ▪ How did you manipulate/modify the info prior to sharing it? What was the purpose of modifying it? ▪ How did you know the info was received by the other person/people? ▪ What challenges did you experience in sharing it? ▪ What info did you need form others? And why was that info important to helping you understand the situation? ▪ How/when did you get it? (if you did get it) ▪ What prevented you (if relevant) from getting it? (or from getting it in a timely manner) • **What if Queries:** ○ Did you consider alternative assessment or explanation? ○ Might someone in the same situation have assessed the situation differently?could the situation be (reasonably) interpreted differently? ○ If current technology was not barrier, what would have helped you make sense of the situation at that point? ○ (if it was an issue of differing interpretations/breakdown in common ground across the team) What could've helped your team be more on the "same page"? How would that have helped?

Appendix H-MHSRS 2013 Presentation

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Foundations of an ICU Decision Support and Collaboration System

US Army Medical Research and Materiel Command
Contract No.W81XWH-12-C-0126.

Presented by

Christopher Nemeth, PhD, CAPT USNR (Ret.)

To

Military Healthcare Research Symposium

Date

15 August 2013

APPLIED RESEARCH ASSOCIATES, INC.
An Employee Owned Company

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Objectives and Identified Gaps

Overall Activity Objectives

e. **Combat Critical Care Engineering** - Explain novel approaches to harnessing the vast amount of data available for decision making in the Emergency Department, Operating Room, and Intensive Care Unit environments on the battlefield.

Identified Gaps

l. **Too much data**, with over-reliance on providers to generate information, needs to be resolved.

m. There is a **need for Decision-Support**, Open-Loop, and Closed-Loop control of critical care functions.

n. Basic and **applied research is required** to discover and develop new knowledge and devices that enhance combat medical personnel capabilities for triage, diagnosis, and decision-making relative to combat casualty management.

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Best Practices

I. Combat Surgical Strategies - Utilize a rich data stream coming from existing and proposed vital signs monitors. Analyze and interpret in a manner which **facilitates decision making** by providers on the battlefield, in accordance with evidence-based medicine and clinical practice guidelines.

Patient Safety and **System Barriers**

Will address:

- Quality and/or patient safety issues
- "System barriers'" that learners encounter when they return to their practice or deployment environment prevent them from implementing what they learn at CME activities.

Photo: Dept. of the Army

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Objectives for This Session

- Understand the nature of cognitive work in an ICU work setting
- Learn how cognitive systems engineering methods are used to develop valid decision support
- Learn individual and team cognitive issues in ICU work setting now under study
- Understand implications of decision and communication support for patient care

Photo: Dept. of the Army

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Research Design

- Goal is to improve care by better supporting the judgment of individuals and teams who care for patients through a cognitive aid that also assists communication.
- Three phases that are scheduled to take roughly a year apiece: foundation research, cognitive aid prototype development, and prototype assessment.
- First year goal: develop a thorough descriptive model of individual and team cognition
- Provide basis for cognitive aid prototype development in the second year, and criteria for prototype assessment in the third year.
- Five 1-week data collection visits at the research site every other month, followed by data analysis sessions four weeks afterward.

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Research Site

- Burn ICU in tertiary care medical center,
- 16 beds, 2 reserved to serve as a post-anesthesia care unit (PACU), 1 dedicated to support Extracorporeal Membrane Oxygenation (ECMO).
- Other nearby units support the ICU, including a step down unit, burn operating room, and outpatient clinic.
- Population averages around 8 patients but as high as 13
- Patients have severe affliction from chemical, mechanical or electrical burns, or burn-like afflictions such as toxic epidermal necrolysis (TENS).
- Length of stay ranges from days to months.

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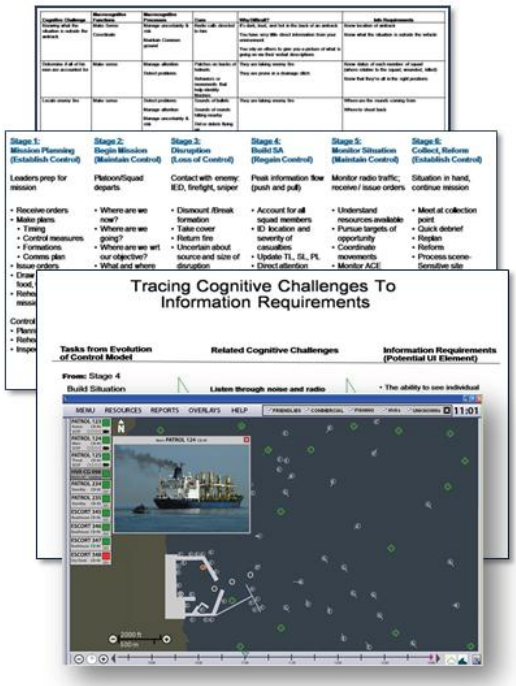
CSE Process Drives End Product

Cognitive work challenges drive functional requirements, and solutions such as clinician cognitive aids



Field data collection leads to

↓

Descriptive cognitive models, to

↓

Decision and information requirements, to

↓

Prototypes to be evaluated and optimized

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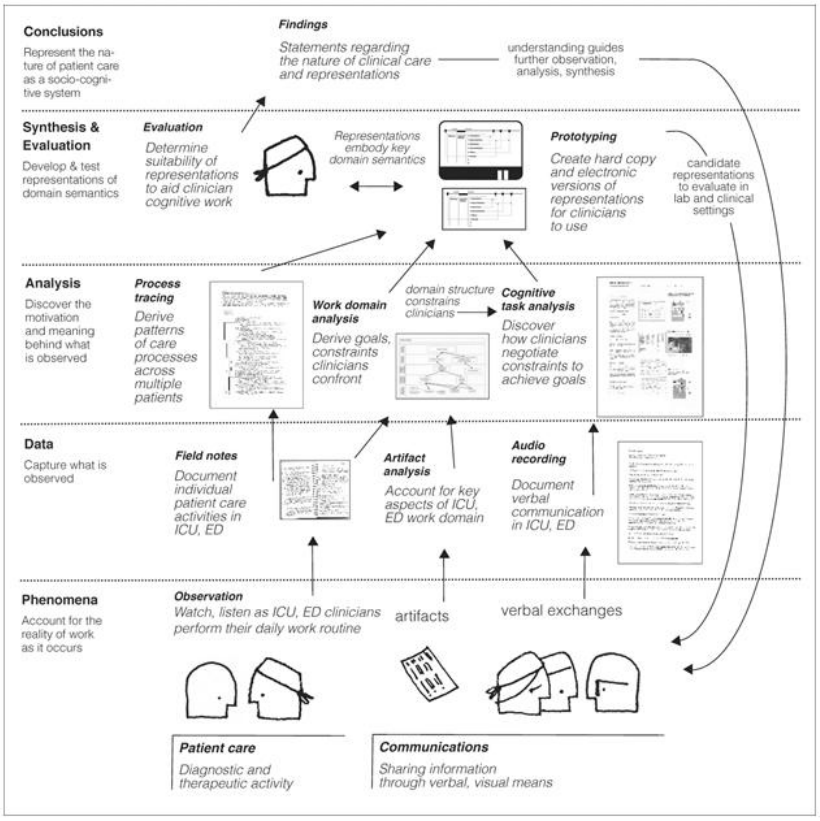
Conclusions
Represent the nature of patient care as a socio-cognitive system
Findings
Statements regarding the nature of clinical care and representations
understanding guides further observation, analysis, synthesis
Synthesis & Evaluation
Develop & test representations of domain semantics
Evaluation
Determine suitability of representations to aid clinician cognitive work
Representations embody key domain semantics
Prototyping
Create hard copy and electronic versions of representations for clinicians to use
candidate representations to evaluate in lab and clinical settings
Analysis
Discover the motivation and meaning behind what is observed
Process tracing
Derive patterns of care processes across multiple patients
Work domain analysis
Derive goals, constraints clinicians confront
domain structure constrains clinicians
Cognitive task analysis
Discover how clinicians negotiate constraints to achieve goals
Data
Capture what is observed
Field notes
Document individual patient care activities in ICU, ED
Artifact analysis
Account for key aspects of ICU, ED work domain
Audio recording
Document verbal communication in ICU, ED
Phenomena
Account for the reality of work as it occurs
Observation
Watch, listen as ICU, ED clinicians perform their daily work routine
artifacts
verbal exchanges
Patient care
Diagnostic and therapeutic activity
Communications
Sharing information through verbal, visual means

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Pop Quiz!

Q. How many work relationships does the BICU bedside nurse maintain?

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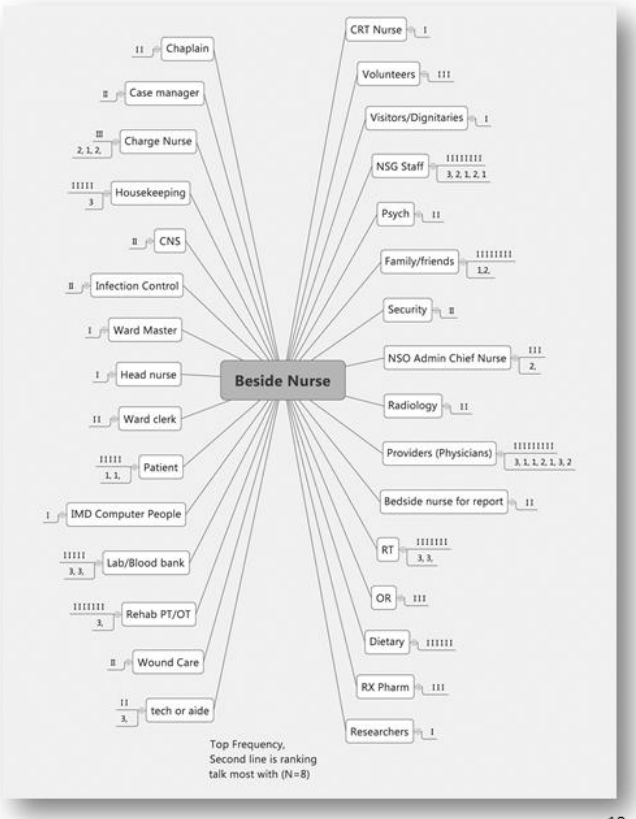
Initial Findings

Q. Number of BICU bedside nurse work relationships?

A. 31



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Information Sources

Databases
Patient Health Record
Outpatient Record
ENDO blood glucose management
CHCS Laboratory Culture
WMSNi Nurse Scheduling Program
IMPACT Radiology Images
WOUND FLOW program
Dietician Excel File
Burn Resuscitation Decision Support
Arterial Blood Gas

CHCS Laboratory Culture
Protocol
White boards
Daily Wound Care Plan
Vital signs flow list
Email/Cell phone
Phone Land Line
Sign-out Sheet
Charge Nurse Checklist

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Next Steps

- Derive quantitative evaluation criteria to compare clinical support tools
- Develop decision, and information, requirements
- Design and develop a prototype compatible with DoD IT requirements
- Test and validate the prototype in concert with other IT solutions that are currently in use
- Field in a clinical setting

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Pop Quiz #2 !

"Medical and diagnostic devices have produced a therapeutic revolution, but in doing so they have also become more complex and less easily understood by those who use them.

When well designed, well made, and properly used they support and lengthen life.

If poorly designed, poorly made, and improperly used they can threaten and impair it."

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Further Thoughts

- Quality and/or patient safety issues
- "System barriers"
  - *Durable, fundamental aspects of work place form practice.*
  - *Change requires extraordinary effort*
  - *Individual initiative requires collaborative support*

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Your comments and correspondence are welcome.

Christopher Nemeth, PhD
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15

Appendix I. Notional Software Architecture

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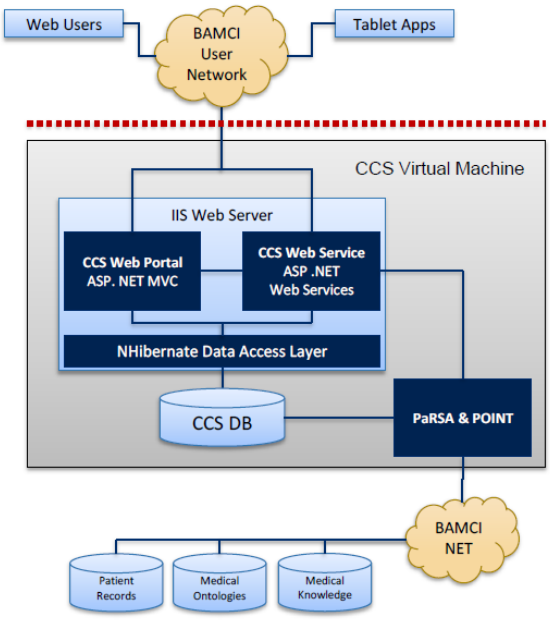
Notional Software Architecture for CCS

- Develop a web site and/or mobile application for CCS
- Service Oriented Architecture (SOA)
  - "Business Logic" implemented as Web Services
  - Accessible from both web site and mobile user interfaces
- Web site using Model/View/Controller (MVC) framework
  - Model shared with web service
  - Controllers leverage web service
- Nhibernate Data Access Layer
  - Object-Relational-Mapping (ORM) common to both web site and web service
- PaRSA and POINT
  - Responsible for backend systems integration
  - Will have access to CCS DB and CCS Web Services



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